EXHIBIT 21

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	C.A. No. 22-252-MSG **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY**
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	

DECLARATION OF ALLISON P. GRISWOLD IN SUPPORT OF MODERNA'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL

I, Allison P. Griswold, hereby declare as follows:

1. I am the Senior Manager, Quality Strategic Operations at ModernaTX, Inc. ("Moderna"). In this role, I am familiar with Moderna's Quality Control ("QC") procedures, including Moderna's compliance with Current Good Manufacturing Practice ("CGMP") standards, FDA criteria and regulations which apply to drugs like Moderna's COVID-19 Vaccine "SpikeVax." I have personal knowledge of the facts stated in this declaration or have become aware of such facts through my role at Moderna. If called upon to testify, I could and would competently testify thereto.

2. I write this declaration in support of Moderna's opposition to Plaintiffs' Motion to Compel production of samples from every drug product batch manufactured of SpikeVax.

3. I understand this case relates to Moderna's COVID-19 Vaccine, known as mRNA-1273 or "SpikeVax." SpikeVax is comprised of messenger RNA (mRNA) which is encased in lipid nanoparticles (LNPs). [redacted]

A. SpikeVax is a Regulated Drug Product that is Approved by the FDA

4. SpikeVax is an FDA-approved drug product, which was initially authorized pursuant to Emergency Use Authorization No. 27073, and later pursuant to Biologics License Application No. 125752. During the FDA approval process, Moderna submits specifications for the drug product and certain of its components, which provide limits for various physical and chemical characteristics. Moderna's specifications for its [redacted] mRNA-LNP, and drug product include lipid content specifications. Each time a batch of [redacted] and drug product is manufactured, Moderna tests a sample to ensure that the batch complies with the specification, including lipid content. A Certificate of Analysis or "COA" is produced each time those tests are carried out, which reports the results of each test to confirm whether it complies with the specification. COAs are also included in Moderna's submissions to the FDA.

5. Because SpikeVax is an FDA-approved drug product, it is subject to regulations. Inventory of batches and samples of drug product and its components is carefully controlled and documented.

B. Request for Samples of Drug Product

6. I have been asked to describe the steps that would need to be taken to be able to produce samples from each batch manufactured of SpikeVax.

7. Retained samples of these batches may be held at Moderna's Norwood location or at third-party manufacturer sites across the United States.

8. I have been part of a cross-functional team that has been working to prepare samples from approximately 400 batches that were manufactured by third-party Catalent to produce to Plaintiffs' external laboratory. The majority of the samples have now arrived at Moderna's facilities, but were previously stored at Catalent's facility in Indiana. The samples had to be driven for over 12 hours under strict cold storage conditions to allow Moderna's team to prepare the samples for production.

9. The team that has been working for weeks to prepare these samples is comprised of at least 15 individuals from various departments, including Quality Control, Quality Assurance, Supply Chain, Compliance, and Regulatory. I expect that an additional 8 individuals will be involved in inventorying the samples, packing the samples for shipment, and documenting their removal from sample retention and processing for shipment.

10. Every process carried out in relation to an approved drug product like SpikeVax requires an approved written Standard Operating Procedure or "SOP." Collection and production of samples for litigation, including by removing regulatory retained samples, is not a standard process that we carry out at Moderna, and as such there is no approved SOP. SpikeVax is Moderna's first commercial product and prior to this request, the company has not had to produce samples for patent infringement litigation.

11. To remove a sample that was reserved for regulatory retain for litigation purposes, the removal must be documented through a change control process, which describes the deviation from normal processes. The change control must be assessed and approved by other stakeholders, including individuals from various departments including Quality Assurance (either internal Quality Assurance, or External Quality Assurance where a contract manufacturing organization is involved), Quality Control, Regulatory, Supply Chain, and Compliance. The change control documentation records the deviation, who evaluated and approved the deviation, and describes the oversight that was involved and what process was followed. The process to be followed is described in a protocol, which for this sample collection must include details on how employees will be trained to follow the protocol, where the samples are being transported to, how they are maintained at required temperatures, and how the temperatures will be monitored.

12. Once an approved protocol is in place, the samples must be inventoried, which is a process where individuals will physically verify the lot numbers of the samples, vial quantities received for each lot and verify that the drug product containers are not damaged. For the drug product, this includes inspecting the samples as they are kept in the freezer at [redacted]. Moderna's Occupational Health and Safety procedures require extensive personal protective equipment to be worn, that two individuals enter the freezer together, and limit the time spent inside the freezer to 15 minutes at a time, and for no more than 60 minutes per shift. To inventory the samples from approximately 400 Catalent lots, I estimate it would take 8-12 hours for three personnel working together, which would have to be conducted over several days due to the restrictions on the amount of time that can be spent in a [redacted] freezer.

13. Once inventoried, the samples must be packed to be shipped at the required cold condition. Again, this requires two people at a minimum going into the freezer and maintaining temperature conditions for the samples. This is a time-consuming exercise as the samples need to be physically packed and the container needs to be pre-conditioned to ensure it can maintain required temperatures during shipment, which, depending on the vendor and container size and availability, requires 1-3 days notice. To prepare to ship the samples from approximately 400 Catalent lots, I estimate it would take another 8-12 hours for three personnel working together.

14. Each of the individuals involved in this exercise is performing these duties on top of their regular roles and responsibilities at Moderna.

15. Further, to the extent any samples that are less than one year past expiry (and are therefore still subject to the regulations that require them to be retained) need to be pulled, each individual sample would require a completed retain authorization before it could be pulled from the storage. This would apply to any product type (e.g. [redacted], DP, etc). Each authorization

would need to be individually approved by a QC Director and QA Director. Given the sample-by-sample requirement, this would become extremely burdensome if Moderna were required to produce large numbers of samples that are not yet one year past expiry.

C. Request for Samples of [redacted]

16. [redacted]

17. [redacted]

18. [redacted]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Executed on this January 4, 2024

Respectfully submitted,

DocuSigned by:
Allison Griswold
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Allison Griswold